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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,416	03/01/2004	Fred H. Burbank	R0367-00106	1476

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EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/790,416	BURBANK ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,29,31-33 and 40-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 29, 31-33, and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed March 13, 2007. Claims 1, 29, 31-33 and 40-51 are pending. Claims 1, 29, 40, 45 and 49 are amended. No new claim has been added. No claim has been cancelled.

Claim Objections

2. The objections are withdrawn due to amendments.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

As used herein the term "system" is intended to mean an apparatus or a method.

4. Claims 1, 29, 31-32 and 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (US Patent No. 5,794,626) in view of Tihon et al. (US Patent No. 5,415,656) further in view of Ritchart et al. (US 5,649,547).

In regards to claim 1, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, having a longitudinal axis and comprising:

a distal end 45 adapted for tissue penetration;

an electrosurgical cutting element 10 which is longitudinally disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to said axis, and which is movable in said radially extended position to isolate a desired intact issue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 15 capable of encapsulating the isolated tissue specimen before its removal from a patient's body (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to claims 29 & 31-32, Kieturakis discloses a method for retrieving a tissue specimen from a patient's body, comprising:

inserting into the patient's body an instrument 5 having a distal end 45, a longitudinal axis, and an axially disposed cutting element 10 so that the distal end 45 is disposed in a tissue region from which the tissue specimen is taken;

radially extending the cutting element 10 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5;

rotating the cutting element 10 about the axis to cut the tissue and create a peripheral boundary about the tissue specimen, to isolate the tissue specimen from surrounding tissue in the tissue region; and

encapsulating the isolated tissue specimen before removing the specimen from the patient's body (see column 2/lines 35-60);

wherein the encapsulating step further includes radially expanding at least one encapsulating element 15 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5 and rotating the instrument 5 about its axis so that the at least one encapsulating element 15 encloses the tissue specimen (see column 2/lines 48-53);

wherein said at least one encapsulating element 15 comprises a plurality of bands which are disposed axially along said instrument 5 (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to claims 40-44, Kieturakis discloses an instrument assembly 5 for isolating a tissue specimen from an intracorporeal site, comprising:

a. an elongate shaft 40 which has a longitudinal axis and a distal end 45; and

b. a tissue cutting component 10 which is radially extendable from a retracted position to an extended position and which is capable of creating a peripheral boundary about the tissue specimen and electrosurgically isolating a desired tissue specimen intact from surrounding tissue at the site; and

c. a tissue collection component 15 coupled to the shaft 40 which is capable of encapsulating the isolated tissue specimen from the surrounding tissue at the site (see fig. 12);

wherein the tissue collection component 15 is capable of maintaining the encapsulated tissue specimen intact (see fig. 12);

wherein the tissue cutting component 10 is longitudinally disposed on the elongate shaft 40 proximal of the distal end 45 of the shaft 40;

wherein the tissue cutting component 10 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen;

wherein both the cutting component 10 and the tissue collection component 15 are movable from a retracted position to an expanded position (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to claims 45-48, Kieturakis discloses an excisional device 5 for cutting and removing a specimen of breast tissue, comprising:

an elongate shaft 40 having proximal and distal portions;

a tissue cutting component 10 which is longitudinally oriented on the distal portion of the shaft, which is configured to cut the specimen of breast tissue from surrounding breast tissue;

a tissue encapsulation component 15 coupled to the distal portion of the shaft 40 which is configured to encapsulate the cut specimen and maintaining the encapsulated specimen intact, both the cutting component 10 and the tissue encapsulation component 15 being movable from a retracted position to an expanded position;

wherein at least one tissue encapsulation component 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3);

wherein the tissue encapsulation component 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24;

wherein the tissue encapsulation component 15 and the tissue-cutting component 10 are configured to expand and retract together (see figs. 2-3).

In regards to claims 49-51, Kieturakis discloses an instrument 5 for encapsulating and removing a tissue specimen from a patient's body, comprising:

a. an elongate shaft 40 which has a distal end 45 a longitudinal axis;

b. a tissue cutting component 10 which is disposed longitudinally on a distal portion of the elongate shaft 40 and aligned with the longitudinal axis, which is radially extendable from a retracted position to an extended position, relative to the longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 2-3 & 12); and

c. an encapsulation component 15 capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing the tissue specimen from the patient's body intact;

wherein the instrument 5 has a distal tissue-cutting element 45 with a linear cutting surface disposed on the distal end of the shaft 40 to facilitate accessing the tissue specimen within the patient's body;

wherein the encapsulation component 15 has a plurality of encapsulation elements, which are radially extendable from a retracted position to an extended position (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

Kieturakis discloses a system, as described above, that teaches all the limitations of the claims except Kieturakis does not teach an electrosurgical cutting step.

However, Tihon et al. disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41).

Ritchart et al. disclose(s) a system, comprising biopsy device wherein an encapsulation component 150 on the distal portion of the instrument is configured to encapsulate the isolated tissue specimen 138c and securing the tissue specimen to the distal shaft portion to facilitate removal of the tissue specimen from the a patient's body along with removal of the instrument (see figs. 1 & 31-34; column 15/lines 21-45).

Applying the factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis with an electrosurgical cutting step similar to that of Tihon et al. in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered

cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. with an encapsulation component that holds the tissue specimen at the distal end similar to that of Ritchart et al. since such a modification would serve the same purpose of capturing and/or removing the tissue sample from the patient's body.

5. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis ('626) in view of Tihon et al. ('656) further in view of Ritchart et al. ('547) even further in view of Kanner et al. (US Patent No. 5,392,790).

Kieturakis as modified by Tihon et al. and Ritchart et al. discloses a method, as described above, that teaches all the limitations of the claim except Kieturakis as modified by Tihon et al. and Ritchart et al. does not teach proximally withdrawing an instrument with the encapsulated tissue specimen from the patient's body.

However, Kanner et al. disclose a method comprising proximally withdrawing an instrument 20 with the encapsulated tissue specimen from the patient's body (see figs. 11-13).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Kieturakis as

modified by Tihon et al. and Ritchart et al. with a method step similar to that of Kanner in order to remove the severed tissue (see Kanner, column 5/lines 2-22).

Moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. and Ritchart et al. with an encapsulation step as claimed since such a modification would amount to design choice that would serve the same purpose of withdrawing the severed tissue from the patient's body. For example, the Applicant has not disclosed that withdrawing the encapsulated tissue specimen with the instrument provides an advantage, is used for a specific purpose, or solves a stated problem

6. Claims 1, 29, 31-33 and 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieturakis (US Patent No. 5,794,626) in view of Tihon et al. (US Patent No. 5,415,656) further in view of Ritchart et al. (US 5,649,547) even further in view of Kanner et al. (US Patent No. 5,392,790).

In regards to claim 1, Kieturakis discloses a biopsy instrument 5 for retrieving body tissue, having a longitudinal axis and comprising:

a distal end 45 adapted for tissue penetration;

an electrosurgical cutting element 10 which is longitudinally disposed on a distal portion of the instrument, which is actuatable between a radially retracted position and a radially extended position, relative to said axis, and which is movable in said radially extended position to isolate a desired intact issue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen, and

an encapsulation component 15 capable of encapsulating the isolated tissue specimen before its removal from a patient's body (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to claims 29 & 31-32, Kieturakis discloses a method for retrieving a tissue specimen from a patient's body, comprising:

inserting into the patient's body an instrument 5 having a distal end 45, a longitudinal axis, and an axially disposed cutting element 10 so that the distal end 45 is disposed in a tissue region from which the tissue specimen is taken;

radially extending the cutting element 10 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5;

rotating the cutting element 10 about the axis to cut the tissue and create a peripheral boundary about the tissue specimen, to isolate the tissue specimen from surrounding tissue in the tissue region; and

encapsulating the isolated tissue specimen before removing the specimen from the patient's body (see column 2/lines 35-60);

wherein the encapsulating step further includes radially expanding at least one encapsulating element 15 so that a portion thereof is radially outwardly spaced from the axis of the instrument 5 and rotating the instrument 5 about its axis so that the at least one encapsulating element 15 encloses the tissue specimen (see column 2/lines 48-53);

wherein said at least one encapsulating element 15 comprises a plurality of bands which are disposed axially along said instrument 5 (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to claims 40-44, Kieturakis discloses an instrument assembly 5 for isolating a tissue specimen from an intracorporeal site, comprising:

d. an elongate shaft 40 which has a longitudinal axis and a distal end 45; and

e. a tissue cutting component 10 which is radially extendable from a retracted position to an extended position and which is capable of creating a peripheral boundary about the tissue specimen and electrosurgically isolating a desired tissue specimen intact from surrounding tissue at the site; and

f. a tissue collection component 15 coupled to the shaft 40 which is capable of encapsulating the isolated tissue specimen from the surrounding tissue at the site (see fig. 12);

wherein the tissue collection component 15 is capable of maintaining the encapsulated tissue specimen intact (see fig. 12);

wherein the tissue cutting component 10 is longitudinally disposed on the elongate shaft 40 proximal of the distal end 45 of the shaft 40;

wherein the tissue cutting component 10 is configured to be rotated at least in part about the longitudinal axis in the radially extended position to isolate the tissue specimen;

wherein both the cutting component 10 and the tissue collection component 15 are movable from a retracted position to an expanded position (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

In regards to claims 45-48, Kieturakis discloses an excisional device 5 for cutting and removing a specimen of breast tissue, comprising:

an elongate shaft 40 having proximal and distal portions;

a tissue cutting component 10 which is longitudinally oriented on the distal portion of the shaft, which is configured to cut the specimen of breast tissue from surrounding breast tissue;

a tissue encapsulation component 15 coupled to the distal portion of the shaft 40 which is configured to encapsulate the cut specimen and maintaining the encapsulated specimen intact, both the cutting component 10 and the tissue encapsulation component 15 being movable from a retracted position to an expanded position;

wherein at least one tissue encapsulation component 15 has a proximal end 23 and a distal end 24 and which is configured to move one end closer to the other end to effect radial extension from the retracted position to the radial extended arcuate position (see figs. 2-3);

wherein the tissue encapsulation component 15 is configured so that the distal end 24 is fixed and the proximal end 23 moves toward the distal end 24;

wherein the tissue encapsulation component 15 and the tissue-cutting component 10 are configured to expand and retract together (see figs. 2-3).

In regards to claims 49-51, Kieturakis discloses an instrument 5 for encapsulating and removing a tissue specimen from a patient's body, comprising:

a. an elongate shaft 40 which has a distal end 45 a longitudinal axis;

b. a tissue cutting component 10 which is disposed longitudinally on a distal portion of the elongate shaft 40 and aligned with the longitudinal axis, which is radially extendable from a retracted position to an extended position, relative to the longitudinal axis, which has an arcuate shape in the extended position and which is movable in the radially extended position about the longitudinal axis to isolate a desired tissue specimen from surrounding tissue by defining a peripheral margin about said tissue specimen (see figs. 2-3 & 12); and

c. an encapsulation component 15 capable of encapsulating the tissue specimen after it has been isolated from surrounding tissue and removing the tissue specimen from the patient's body intact;

wherein the instrument 5 has a distal tissue-cutting element 45 with a linear cutting surface disposed on the distal end of the shaft 40 to facilitate accessing the tissue specimen within the patient's body;

wherein the encapsulation component 15 has a plurality of encapsulation elements, which are radially extendable from a retracted position to an extended position (see figs. 1-3 & 12; see abstract; see column 2/lines 16-34 & 48-60; column 6/lines 13-19; column 7/lines 13-15 & 62-67; column 8/lines 1-14).

Kieturakis discloses a system, as described above, that teaches all the limitations of the claims except Kieturakis does not teach an electrosurgical cutting step.

However, Tihon et al. disclose an apparatus comprising an electrosurgical cutting wire 1, energized by radio frequency (RF) energy; wherein an electrical conductor 35 having a distal end electrically connected to the electrosurgical cutting element and a proximal end configured to be connected to a source ESU to deliver radio frequency energy from the source to the electrosurgical cutting element (see figs. 2 & 8; column 1/lines 65-68; column 2/lines 1-5 & 20-31; column 3/lines 21-33; column 5/lines 56-64; column 8/lines 32-41).

Ritchart et al. disclose(s) a system, comprising biopsy device wherein an encapsulation component 150 on the distal portion of the instrument is configured to encapsulate the isolated tissue specimen 138c and securing the tissue specimen to the distal shaft portion to facilitate removal of the tissue specimen from the a patient's body along with removal of the instrument (see figs. 1 & 31-34; column 15/lines 21-45).

Kanner et al. disclose a method comprising proximally withdrawing an instrument 20 with the encapsulated tissue specimen from the patient's body (see figs. 11-13).

Applying the factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis with an

electrosurgical cutting step similar to that of Tihon et al. in order to make the cutting operation easier, more direct and thus less traumatic, than cutting with an unpowered cutter. Moreover, use of RF powered cutting element permits the convenient application of coagulating power for hemostasis (see Tihon et al., column 1/line 65 to column 2/line 5).

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. with an encapsulation component that holds the tissue specimen at the distal end similar to that of Ritchart et al. since such a modification would serve the same purpose of capturing and/or removing the tissue sample from the patient's body.

Even moreover yet, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Kieturakis as modified by Tihon et al. and Ritchart et al. with a method step similar to that of Kanner in order to remove the severed tissue (see Kanner, column 5/lines 2-22).

Furthermore, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kieturakis as modified by Tihon et al. and Ritchart et al. with an encapsulation step as claimed since such a modification would amount to design choice that would serve the same purpose of withdrawing the severed tissue from the patient's body. For example, the Applicant has not disclosed that withdrawing the encapsulated tissue specimen with the

instrument provides an advantage, is used for a specific purpose, or solves a stated problem.

Response to Arguments

7. Applicant's arguments filed March 13, 2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RTT

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